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Instructions for offering STARHS / the LS-EIA test HIV Incidence Projects information sheet

Your client had a positive HIV test and is eligible for an experimental test that may indicate how recently s/he might have been infected with HIV. This test is free and requires no additional blood to be drawn. The test is may be called the less-sensitive EIA (LS-EIA) or STARHS. The HIV Incidence Projects have been funded by the Centers for Disease Control and Prevention. STARHS, along with other information, may help your client to decide about HIV treatments and partner notification, and also may help public health officials to determine how the HIV epidemic is spreading. Because STARHS is investigational, consent is required. We are requesting verbal consent. You will receive a call from surveillance staff (who were notified by the laboratory that there was an HIV+ result) to remind you to offer STARHS at the post-test visit. Please follow these steps to provide to request your client's consent for this research:

- Ask your client for consent for this research when you give the standard HIV test results.
 Explain there is an experimental test called STARHS that is available that may help public health officials determine how the HIV epidemic is spreading.
- Give the study information sheet to the client to read and ask for his/her consent to participate in the study. Go over the entire form with him/her. Be sure the client has an opportunity to ask questions. Key points to stress at time of consenting are that the project is voluntary. STARHS is done with leftover blood, no new blood draw is needed. The STARHS method was developed to look at new infections in groups of people, not individuals. The less sensitive HIV test has not been approved by the Food and Drug Administration (FDA). STARHS is experimental; that means we don't know how accurate it is. STARHS is not meant to be used for medical care.
- Because you are not drawing blood for STARHS, do not submit another laboratory requisition form.

Call research staff at (206) 205-1470 to let us know of your client's decision whether to participate in the research. We will contact the lab to let them know to run STARHS.

- There is no need to send the information sheet to research staff.
- We will try to get STARHS results to you in a week, although it can take longer, depending on the availability of test kits. If your client wants to know his/her STARHS results, please read the brief self-instructional training manual on the web first: http://www.metrokc.gov/health/apu/starhs/. If inform your clients of STARHS results, the key points to discuss are that STARHS was developed to look at new infections in groups of people, not individuals. STARHS is not approved by the Food and Drug Administration (FDA). We don't know how accurate it is. A non-reactive result only suggests a client may have become infected in the past year. A reactive result is interpreted as inconclusive, or that it is not known when the client may have become infected.





If you want more information, research staff are available to answer any questions you have.

Call (206) 205-1470 or email libby.charhon@metrokc.gov

Suggested post-post test counseling IN-PERSON script for approaching eligible subjects by C&T Staff for requesting LS-EIA/STARHS research consent:

Here is an information sheet about an experimental HIV test. Let's go over it together.

<After client has read the entire information sheet or has had it read to him/her>

"Do you have any questions? [answer questions, then ask] "Would you be willing to have your leftover blood tested with **STARHS**?"